

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 1-11 are pending in the application.

Request to Acknowledge Receipt of Certified Copy

As a preliminary matter, counsel notes that the examiner has not acknowledged receipt of a certified copy of the priority document in this national stage application from the International Bureau; *see* Office Action Summary, item 12) a) 3. In fact, the priority document is part of this file as acknowledged in the Notice of Acceptance of Application Under 35 U.S.C. §371 and 37 C.F.R. §1.495 letter mailed March 13, 2007. This letter states is was filed on April 20, 2006.

Applicants provided a certified copy to the Receiving Office under PCT Rule 17 and the International Bureau forwarded a copy to each of the designated offices. See also M.P.E.P. § 1893.03(c). Therefore, in accordance with M.P.E.P. § 1896 III, the Examiner is respectfully requested to consult with the Special Program Examiner in his/her Technology Center to obtain a certified copy of the priority document. Also see PCT Rule 17.2 which states, "No such Office shall ask the applicant himself to furnish it with a copy."

The examiner is requested to acknowledge receipt of the priority documents in the next communication.

Response to Claim Rejection – 35 USC §112, Paragraph 1

The examiner regards as enabled the use of TEMPO for the oxidation of Solketals.

The examiner argues that the specification does not reasonably provide enablement for the generically claimed TEMPO-derivative of formula 1 – it is only the derivatives that are concerned with this rejection. The examiner suggests that the formula 1 encompasses many structures containing many functionalities as well as Y variables, whereas the TEMPO would have no functionality other than simple alkyl groups at the 2 and 6 positions of the piperidine base core structure.

As regards the substituted TEMPO, the examiner recites the *Wands* factors but does not really analyze them, making only generalized statements, usually with no supporting evidence. "In order to make a rejection [over lack of enablement], the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention." *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also* MPEP

§2164.04. A “reasonable basis” must reply on acceptable evidence: “it is incumbent upon the Patent Office … to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with *acceptable evidence or reasoning* which is inconsistent with the contested statement.” *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971) (emphasis added, citations omitted).

In applicants’ view, the considerations provided are mostly statements/assertions and the examiner does not provide substantial evidence in support of them. E.g., as an example, the examiner argues that the art of organic chemistry is unpredictable and that success in any given chemical transformation depends on many variables including the nature of the reagent. The examiner suggests that it is unpredictable whether the claimed efficiency with TEMPO will be obtained when TEMPO derivates are used in place of TEMPO. However, the examiner does not provide substantial support for such a suggestion. On these points the rejection seems to be mainly based on assumptions.

As a further example, under the “state and predictability of the art,” the examiner simply states “The art of organic chemistry is unpredictable and success in any given chemical transformation depends on many variables including the nature of the reagent” without offering *any* evidence or supporting basis for such a statement.

It is also argued “The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the art of organic chemistry, it is noted that each embodiment of the invention (tempo derivatives) is required to be individually assessed for viability.” indicating assessments will be needed. Such assessments do not detract from enablement, for as *Wands* itself notes, “a considerable amount of experimentation is permissible, if it is merely routine.” 858 F.2d at 737; *see also* MPEP §2164.06.

As to “working examples” it is argued that those in the specification are limited to TEMPO. “It is not seen where in the specification the applicability of other derivatives for the oxidation is demonstrated. Though the oxidation of alcohols by TEMPO is well known, because of the sensitivity of the particular alcohol Solketals substrate, it is unpredictable whether the claimed efficiency with TEMPO will obtain when TEMPO derivatives are used in place of TEMPO.” In fact, the Action does not demonstrate by evidence or reasoned argument why the

converse of this is not true – there is nothing of record to demonstrate the TEMPO derivatives (in place of TEMPO) would not be suitable.

The specification also provides considerable guidance for the choice of inert base, temperature, N-chloro compounds, solvents, etc. See pages 2-5 of the description as well as other passages.

Further responding, in EP 0775684 A1, several TEMPO derivatives have successfully been applied for the oxidation of primary and secondary alcohols. Thus, pending clear evidence applicants submit that TEMPO derivatives show similar efficiencies as compared to TEMPO. More specifically for the Y variables in formula 1, it will be noted that the groups of general formulae d, e and f from the definition of Y are all related molecules. In prior art EP 0775684 reference is made to the article of Anelli et al (*J. Org. Chem.* 1987, 52, p. 2559-2562). As was described in Anelli et al (p. 2559, right column 'it has been ...' to p. 2560, left column '... two-phase conditions') (a copy of this article is attached) groups of the general formulae d, e and f from the definition of Y change into one another during the oxidation cycles. This means that groups of general formulae d and e from the definition of Y are inherently present in the reaction mixture when using the group of general formula f. Since groups of the general formulae d and e are either less stable or commercially less available than f, examples have been performed using the group of the general formula f. However, to have a fair scope of protection for the present application, and in view of the explanation given above (substantiated by literature) applicants deem it justified to include groups of the general formulae d and e from the definition of Y in the claims.

The claims now under examination are enabled for not only TEMPO but over their full range. Reconsideration of this rejection and withdrawal of same are in order and are respectfully requested.

Response to Claim Rejection – 35 USC §103(a)

According to the examiner claims 1-11 of the present application are rejected under 35 USC §103(a) as being unpatentable over EP 0775684 A1.

The examiner asserts that one skilled in the art of organic chemistry, exploring different methods of oxidizing solketal (2,2-dimethyl-1,3-dioxolane-4-methanol) would be motivated to try many reagents, including TEMPO. The instantly claimed invention of using TEMPO would

have been suggested – so it is argued – because of the teachings of EP 0775684 A1 (published 1997). This is not so.

The examiner states that a “strong case” of *prima facie* obviousness has been established. To establish a case of *prima facie* obviousness three major requirements should be addressed. One of these requirements is that there must be a reasonable expectation of success. On basis of the following it is apparent this requirement has not been met.

In a later¹ publication by Ermolenko et al (*Synlett*, 2001, 10, p. 1565-1566) it is explicitly stated at page 1565, left-hand column, second paragraph, that TEMPO is not capable of catalyzing the oxidation of 2,2-dimethyl-1,3-dioxolane-4-methanol to glyceraldehydes acetonide. A copy of this article, identified and discussed at page 2 of the subject application, is attached.

On the contrary, in the present application it has been shown that TEMPO does catalyze the oxidation of 2,2-dimethyl-1,3-dioxolane-4-methanol. Additionally, the present application shows that this TEMPO oxidation results in a higher yield as compared to the PCC oxidation which is suggested by Ermolenko et al – in fact, this publication teaches away from the invention.

So, even if the person skilled in the art would be motivated to try many oxidation agents, based on the publication of Ermolenko et al, he would not expect to have success when using TEMPO for the oxidation of 2,2-dimethyl-1,3-dioxolane-4-methanol.

It will be apparent then, there is no *prima facie* obviousness, and the claims as filed are novel and inventive over the prior art.

Two literature articles were discussed in the above remarks and comments. In order to complete the record and have them properly cited submitted herewith (in addition to copies of these articles) is a PTO form PTO/SB/08a so the documents will be listed on the face of any patent issuing on this application.

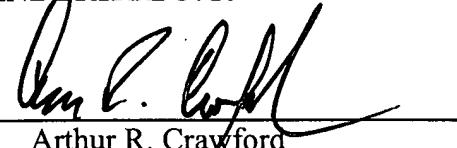
For the above reasons it is respectfully submitted that the claims of this application are enabled for the full scope of the claims as filed and define subject matter that is both novel, inventive and therefore patentable. Should the examiner require further information, please contact the undersigned.

¹ That is later than the 1997 publication date of EP 0775684 A1.

QUAEDFLIEG et al
Appl. No. 10/576,447
April 3, 2008

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100